

Remarks:

Claims 3-4 and 7-31 remain for consideration in this application with claims 12, 19, 26 and 31 being in independent format. Applicant respectfully asserts that in view of the amendments and remarks herein, the rejections of the Office Action dated May 5, 2005 are traversed or should be withdrawn.

In the Action, all claims were rejected under 35 U.S.C. § 112, second paragraph for indefiniteness. Specifically, claim 12 was rejected for a lack of antecedent basis for the phrase "HCV antigen", indefiniteness of the distinction between the "biological fluid sample" and the "second fluid sample. The lack of antecedent basis for HCV antigen has been remedied by the amendment as has the rejections based on the phrases "biological fluid sample" and "second fluid sample." Claim 19 was also specifically rejected under 35 U.S.C. § 112, second paragraph for indefiniteness for allegedly being indefinite for the claimed steps. Applicant asserts that claim 19, as amended, is fully definite. The phrase "predicting whether or not the individual has chronic HCV based on said correlation" has been added to the claim to provide a resolution step wherein the correlating step and comparison step are related. This amendment also cures the rejection based on the omission of an essential step. This is because the HCV antigen in the sample will contribute to the optical density. Thus the claim merely states that you have a fluid sample, you add an ingredient, measure the optical density of the solution created by the fluid sample and ingredient, and correlate the optical density with whether or not the individual has chronic HCV.

Claim 30 was alleged to be indefinite in the recitation of "said sample contains chronic HCV infection." This claim has been amended to note that the sample is from an individual and that the result is to determine whether the individual providing the sample has chronic HCV infection.

Finally, claim 31 was rejected for its recitation of "said assay including antigen to HCV antibodies." This phrase has been amended to the singular form to provide additional clarity. With respect to the rejections for the lack of nexus between the "performing" and "determining" steps, Applicant asserts that such a nexus is in the claim. Specifically, claim 31 has the limitation of "using the optical density to predict whether the individual has chronic HCV infection by comparing the determined optical density with a correlation curve based on the optical densities of fluid samples in combination with HCV antigen from an HCV antibody-based assay from individuals having chronic HCV infection and individuals that have cleared the HCV infection but still test positive for HCV antibodies." Such a limitation fully explains the nexus and how the claimed method is used.

In view of these amendments and arguments, Applicant asserts that all indefiniteness issues have been overcome.

All claims were rejected under 35 U.S.C. § 103(a) as being unpatentable over WO 00/26673 to Scheffel et al. (Scheffel). Specifically, it was alleged that one of skill in the art would have been motivated to substitute the disclosure in Scheffel of using optical density as a measure of antibody concentration for the present application's use of optical density alone as a predictor of chronic HCV infection. Applicants note that a prima facie case under section 103 requires that the suggestion to modify the cited reference be included in the reference itself. No such suggestion is contained in Scheffel. Accordingly, for this reason alone, this rejection is overcome.

If any questions should remain, the Examiner is encouraged to contact the undersigned at 1-800-445-3460.

Any additional fee which is due in connection with this amendment should be applied against our Deposit Account No. 19-0522.

In view of the foregoing, a Notice of Allowance appears to be in order and such is courteously solicited.

Respectfully submitted,

By

A handwritten signature in black ink, appearing to read "Tracey S. Truitt", written over a horizontal line.

Tracey S. Truitt, Reg. No. 43,205
2405 Grand Boulevard, Suite 400
Kansas City, Missouri 64108
816/474-9050

ATTORNEYS FOR APPLICANT